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(71)(72) Applicant and Inventor: SKALKEAS, Grigorios [GR/GR]; 9 Kanari, GR-106 71 Athens (GR).

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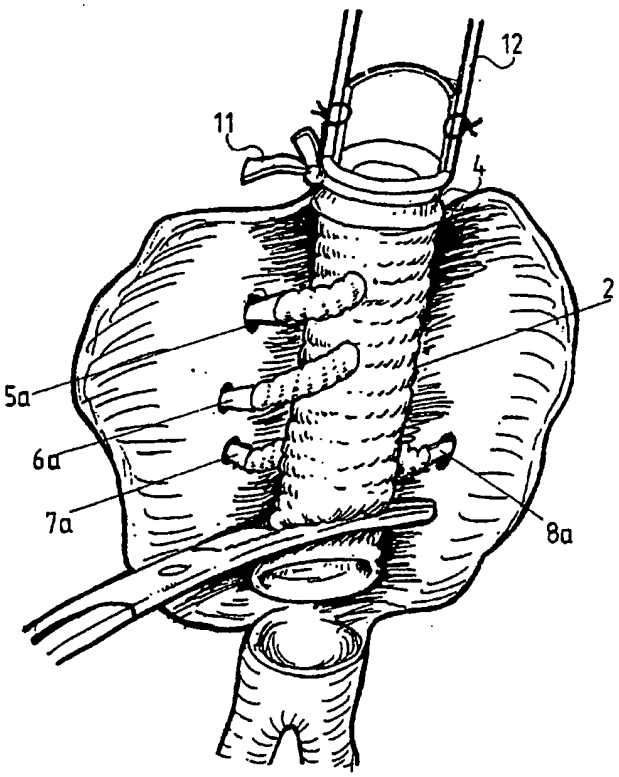
(54) Title: VASCULAR GRAFT FOR THE REPLACEMENT OF THE UPPER ABDOMINAL ASCENDING AORTA AND OF THE AORTIC ARCH

(57) Abstract

A vascular graft suitable for the replacement of the upper abdominal ascending aorta and of the aortic arch is described. This graft bears a number of peripheral branches ending in convergent orifices. In the course of surgical operations, the proposed vascular graft is used in order to achieve continuity of blood supply to the "noble" organs of the organism (the liver, the kidneys, etc.) which are susceptible to irreversible damage should blood supply be interrupted for long time periods. The immediate restoration of blood supply is achieved by the insertion of the above-mentioned orifices of the branches of the graft into the respective arteries, following the insertion and securing of the proximal end of the graft which is provided with a rigid ring and a protruding semi-rigid part into the proximal stump of the aorta.



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Vascular graft for the replacement of the upper abdominal ascending aorta and of the aortic arch.

THE FIELD OF THE ART

The present invention relates to the field of the art concerning vascular grafts. The invention introduces the use of a special graft for the replacement of the aortic arch and of the upper abdominal ascending aorta.

THE PRIOR ART

None of the currently used techniques utilizes vascular grafts similar to the one proposed by the present invention.

The Aorta is the duct which transports blood from the heart to the organs. It is widely known that all the important visceral arteries originate from the part of the aorta between the abdomen and the thorax. Such visceral arteries supply blood to the liver, the kidneys, the spleen etc. This is quite important because the blood circulation in "noble" organs (the spleen, the liver, the pancreas, the stomach, the kidneys, the small and the large intestine) should not be stopped during surgical operations. It has been proved that the time period between the interruption of blood circulation in a "noble" organ and the final necrosis of the organ is strictly limited. For the liver, for example, this period can be less than 30 minutes.

However, current techniques dealing with the problem of rapid visceral revascularization are rather ineffective when the said organ is not supplied with blood by a visceral artery originating from a healthy area on the walls of the aneurysm

(cuff). Specifically, currently used solutions involve the anastomosis of each and every visceral artery (e.g. the classic tubular graft transplantation), which is a time consuming operation often resulting in the necrosis of the organ, followed by the inevitable death of the patient.

Moreover, even in cases where the above problem is possible to be solved by the preservation of the part of the wall of the aneurysm carrying the orifices of the visceral arteries, the remaining part of the aneurysm (which is usually pathological) will probably cause new problematic situations in the future.

All the above, evidently, constitute dangerous drawbacks as to the effectiveness of the described methods, as well as dangers concerning the life span of this therapeutic technique.

It is therefore an object of the present invention to deal with the drawbacks and disadvantages of the techniques of the prior art. The proposed solution is a special vascular graft and a method for its rapid plantation, so as to achieve the practically immediate visceral revascularization, providing blood supply to the organs that are very sensitive to prolonged ischaemia (noble organs), during surgical operations for the replacement of the aortic arch and/or the upper abdominal ascenting aorta.

In accordance to a preferred embodiment of the invention a specially designed artificial graft is used for the replacement of the upper abdominal ascending aorta. On its

upper end, which is inserted in the proximal aortic stump, the proposed graft bears a hard ring and a semi-rigid flap. The inferior part of the graft can be bifurcated for anastomosis to the iliac and/or the femoral arteries and into the main arteries which are necessary to be revascularized. A corresponding form of vascular graft is proposed for the replacement of the aortic arch.

All the characteristics and advantages of the present invention are explained in depth in the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be made apparent to those skilled in the art by reference to the accompanying drawings, which depict illustrative and not confining embodiments of the invention.

Figure 1 illustrates an indicative perspective view of the proposed graft for the replacement of the abdominal aorta.

Figure 2 illustrates an indicative perspective view of the above illustrated graft connected with the abjacent visceral arteries.

Figure 3 illustrates an indicative perspective view of the graft used in accordance to the present invention for the replacement of the aortic arch.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The following paragraphs contain an indicative description of preferred embodiments of the present invention, made by reference to the accompanying drawings.

Figures 1 and 2 illustrate an indicative embodiment of the abdominal aorta graft 1 proposed in the present invention. The proposed graft is made of DACRON, or any other suitable material, and has the form of a cylindrical duct 2 with a diameter of about 20-24 mm and a length varying according to the physical proportions of the patient's body. The graft extends between an upper (proximal) orifice and a lower orifice 10. The upper end 9 of the graft is provided with a rigid ring 4 and is inserted in the proximal stump 12 following division of the aneurysm. There it is secured by an appropriate stitch 11 forming an intravascular graft. The protruding semi-rigid part 3 of the graft extends upwards in the stump securing and stabilizing the joint. For maximum endurance of the joint, this extension may be secured on the walls of the aorta by stitches.

The cylindrical body 2 of the graft bears a number of branches positioned lengthwise in locations corresponding to those of the arteries to be revascularized. The number of the latter determines the number of the branches of the graft. The graft 1 is illustrated with an indicative number of four branches. The first branch (from top to bottom) is used for anastomosis with the celiac artery and is 5-8 mm in diameter and 5 cm in length (measured from the internal surface of the graft). The distance of the first branch 5 from the rigid ring 9 may vary. The second branch 6 which will be connected to the superior mesenteric artery is 8-9 mm in diameter, 5 cm in length (measured as above), and orginates 8-10 mm from the

origin of the overlying first branch 5. Whilst the branches for the celiac and the superior mesenteric arteries are located one below the other in the same vertical plane, the next two branches 7 and 8 which serve the needs of the two renal arteries, are located in facing positions, underneath and at an angle to the above. Each of the two branches 7 and 8 supplying the renal arteries is about 7 mm in diameter and its free edge extends 5 cm from the internal surface of the graft whilst each one of them originates at a position 1-2 cm below the origin of the branch supplying the superior mesenteric artery. The inferior end 10 of the graft may divide into anastomotic branches for the ileal or the femoral arteries.

According to a preferred embodiment of the invention all the branches end up into rigid tapered plastic orifices. These orifices, illustrated as items 5a, 6a, 7a, and 8a respectively can be rapidly inserted into the corresponding orifices of the arteries from the inside of the aneurysm, right after the conclusion of the proximal anastomosis, thereby restoring the blood supply to the viscera in time.

The introduction of the described graft proposes new surgical techniques, which will utilize the advanced characteristics of the graft, achieving the immediate restoration of blood supply, in organs which are sensitive to prolonged ischaemia.

Specifically, the proposed new technique consists of the following stages:

Insertion and securing of the upper end of the graft into the proximal stump of the aorta after the division of the aneurysm.

Localization of the visceral arteries followed by anastomosis with the branches of the graft, resulting in the restoration of blood supply to the viscera. The abovementioned connection is achieved with the following operations: At first, the convergent orifices mentioned in the above paragraphs are inserted into the corresponding orifices of the arteries. Then, the convergent orifices are secured into the arteries by an appropriate tape, surrounding the joint. This achieves the practically immediate restoration of blood supply to the viscera. The full anastomosis of the arteries to the corresponding visceral branches of the artificial graft is then possible, while blood circulation in the vessels is completely normal.

Figure 3 illustrates another proposed graft according to the invention, which is intended to replace the ascending aorta and the arch of the aorta 13. The graft is made of any suitable material, e.g. DACRON, and is an arch like bent cylindrical duct 14 with a proximal and a distal end, 15 and 16, respectively. The graft extends to a length of about 12 cm, whereas the diameter of its proximal orifice 15 is 25-30 mm and the diameter of its distal orifice 16 is 18-20 mm. The proximal end 15 of the graft is provided with a rigid connection ring 17 and, if necessary, an artificial or other type of valve 18 for the replacement of the aortic valve.

The branches of the proposed graft 13, which originate along the superior surface of the cylindrical duct 14 are the following:

a) The graft 19 replacing the innominate artery. It originates 5-6 cm from the rigid ring 17 and extends to a length of about 5 cm, whilst its diameter is about 13 mm and its edge bears a convergent orifice of gradually decreasing diameter 19a. b)The graft for the replacement of the left common carotid artery 20. It originates at a distance of 3-4 cm from the innominate artery graft 19, and ends up at a convergent orifice 20a similar to the above. Its length and diameter are 5 cm and 9-10 mm respectively.c) The subclavian artery graft 21 which originates at a distance of 3-4 cm from the common carotid graft 20. This is about 5 cm long, has a diameter of about 9 mm and ends up in a convergent orifice similar to the ones described above.

It should be noticed that the above description and examples are indicative and do not limit the possible applications of the invention. Consequently, any modifications or alteration in the shape, size and dimensions of the grafts, as well as any other changes in the materials and parts used in the described applications, as long as they do not constitute an inventive step, are considered to be part of the scope and aims of the present invention.

CLAIMS

1. Vascular graft for the replacement of the upper abdominal ascending aorta and of the aortic arch, characterized by that it ensures the immediate restoration of blood supply to organs that are sensitive to prolonged ischaemia, and comprises a proximal end equipped with a rigid ring and a semi-rigid flap to be inserted into the proximal aortic stump, said vascular graft further comprising a plurality of visceral branches, each one of said visceral branches ending up to a rigid convergent orifice being rapidly inserted into the corresponding orifices of dissected arteries, thereby ensuring immediate visceral revascularization.

2. Vascular graft (1) for the replacement of the upper abdominal ascending aorta, according to claim 1, characterized by that it comprises a cylindrical duct (2) extending between a proximal end (9) and a distal end (10), said graft incorporating a rigid ring (4) which is inserted into the proximal aortic stump produced by the dissection of the aneurysm (12) and a semi-rigid flap (3), wherein a plurality of visceral revascularizating branches supplying main vessels originate along said cylindrical duct (2), said plurality of branches including at least one of the following:

.branch (5) with a convergent orifice (5a), supplying the celiac artery;

.branch (6) with a convergent orifice (6a) supplying the superior mesenteric artery;

.a pair of branches supplying the renal arteries (7,8), said two branches (7,8) originating from facing positions, underneath and at an angle to the above said branches (5) and 6, said branches (7,8) ending to convergent orifices (7a,8a), wherein the distal end (10) of said graft divides into branches which will supply the iliac and/or the femoral vessels.

3. Vascular graft (1) for the replacement of the upper abdominal ascending aorta, according to claim 2, wherein the length of said cylindrical duct (2) of the graft can vary and its diameter ranges from 20 to 24 mm, and wherein the length of each one of said branches of the graft is about 5 cm, measured from the internal surface of the cylindrical duct (2), the positions and the dimensions of said branches (5,6,7,8) being as follows:

.the distance of the origin of the celiac artery branch (5) from said rigid ring (4) varies according to the physiologigal dimensions of the patient's body and its diameter is about 5-8 mm;

.the superior mesenteric artery branch (6) has a diameter of 8-9 mm and originates 8-10 mm from said celiac artery branch (5);

.the renal artery branches (7,8) have a diameter of 7 mm each and originate at a distance of 1-2 cm from said superior mesenteric branch (6).

4. Vascular graft (13) for the replacement of the ascending aorta and the aortic arch, according to claim 1,

said graft romprising an arch-like bent cylindrical duct (14) with a proximal end orifice (15) and a distal end orifice (16), said cylindrical duct (14) incorporating a rigid ring (17) used for the anastomosis of the graft with the dissected aneurysm, wherein at least one of the belowmentioned branches originates along said cylindrical duct(14):

.the innominate artery branch (19) which ends up to a convergent orifice (19a);

.the left common carotid branch (20) which ends up to a convergent orifice (20a);

.the left subclavian artery branch (21) with a convergent orifice (21a).

5. Vascular graft (13) for the replacement of the ascending aorta and the aortic arch, according to claim 4, wherein an artificial valve (18) can be attached at its proximal end (15) for the replacement of the aortic valve.

6. Vascular graft (13) for the replacement of the ascending aorta and the aortic arch, according to claims 4 and 5, wherein said cylindrical duct (14) of the graft is about 12 cm long and its diameter varies from 25-30 mm at its proximal end (15) to 18-20 mm at its distal end (16), and wherein each of said branches of said graft (19,20,21) is about 5 cm long measured from the external surface of said cylindrical duct (14), the positions and dimensions of said branches being the following:

.the innominate artery branch (19) originating at a distance of 5-6 cm from said rigid ring (17) and its diameter

is about 13 mm;

.the left common carotid branch (20) having a diameter of 9-10 mm and originating 3-4 cm from the innominate artery branch (19);

.the left subclavian artery branch (21) being about 9 mm in diameter and originating at a distance of 3-4 cm from said left common carotid branch (20).

7. Surgical technique for the replacement of the upper abdominal ascending aorta and/or the aortic arch, characterised by that it uses vascular grafts which ensure rapid visceral revascularisation and blood supply to organs that are sensitive to prolonged ischaemia, said surgical technique consisting of the hereinbelow mentioned stages:

.insertion of said vascular graft into the proximal aortic stump, the proximal part of the graft being inserted into the stump bearing a rigid ring and a semi-rigid flap for better adjustment into said proximal aortic stump, said graft further being provided with branches which end up into convergent orifices of hard plastic material, said graft being inserted into the proximal stump produced by the dissection of the aneurysm and being stabilised therein by an appropriate stitch, said semi-rigid flap of said graft protruding into the stump and being secured on the walls of the aorta by a plurality of stitches;

.localisation of the vessels needed to be revascularised and connection of these to said branches of the graft, said connection being achieved with the insertion of the hard

convergent orifices of said branches into the dissected corresponding vessels, thereby achieving rapid visceral revascularisation;

.stabilisation and securing of each one of said convergent orifices into the orifices of the dissected arteries by a film surrounding the joint, allowing for the full anastomosis of the vessels to the corresponding branches of the artificial graft, whilst blood circulatiom in the vessels is completely normal.

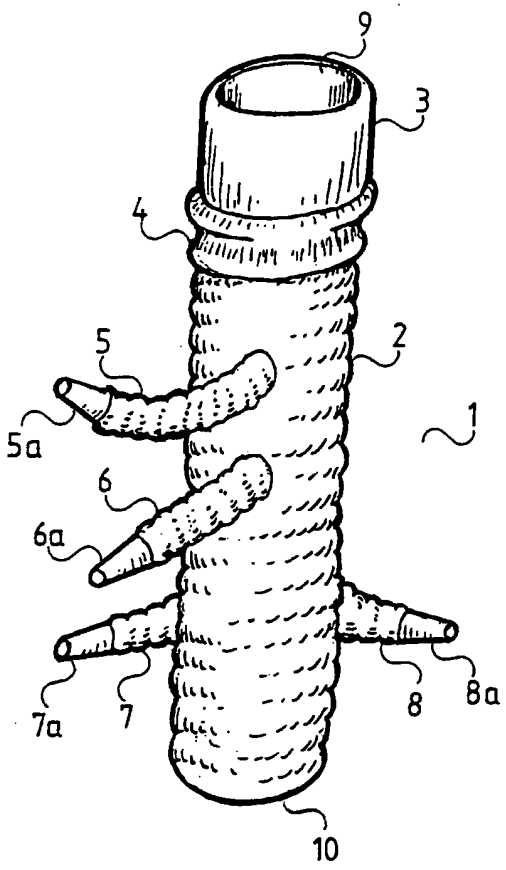

FIG. 1.

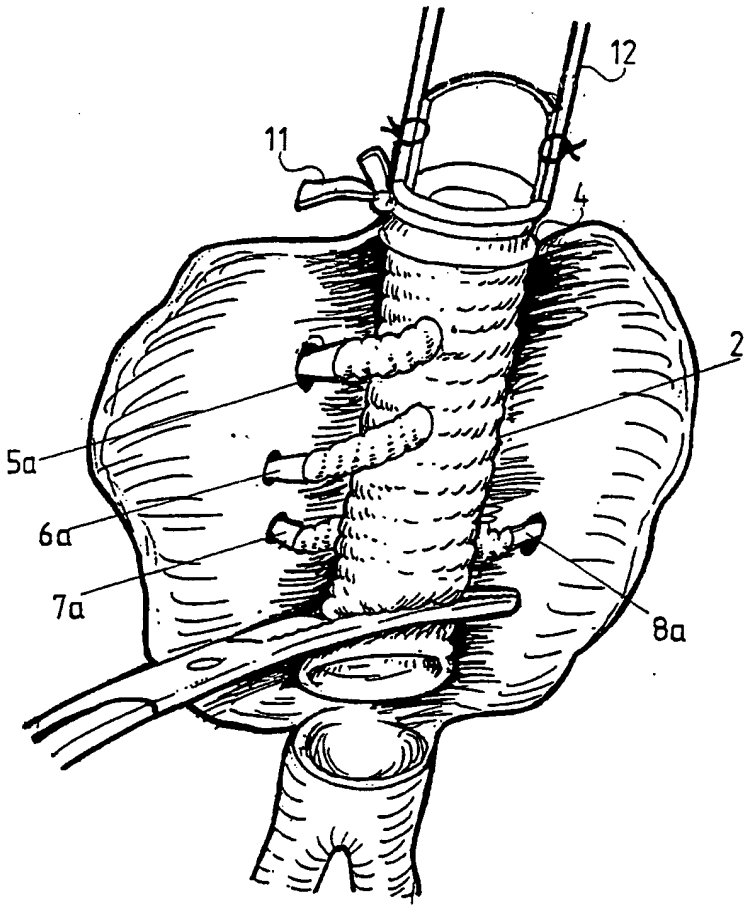

FIG. 2.

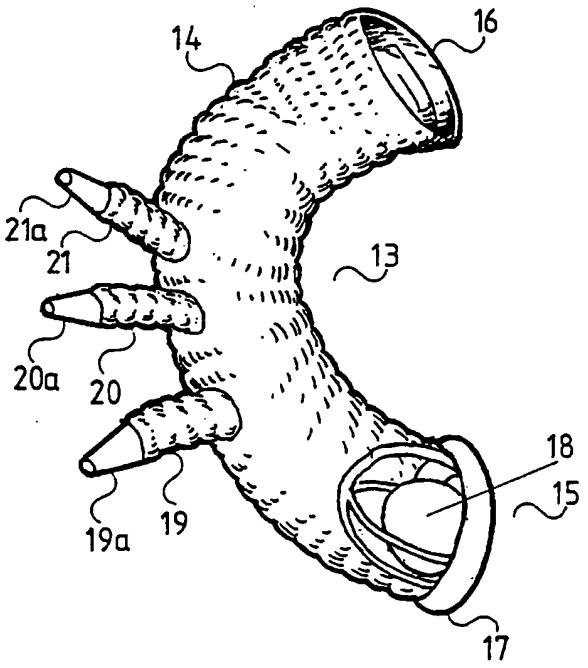

FIG. 3.

INTERNATIONAL SEARCH REPORT

Inter. onal Application No
PCT/GR 94/00019

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,4 313 231 (KOYAMADA) 2 February 1982 see the whole document	1-6
Y	US,A,5 123 919 (SAUTER ET AL.) 23 June 1992 see column 2, line 62 - column 4, line 5; figures	1-6
A	US,A,5 178 634 (RAMOS MARTINEZ) 12 January 1993 see column 3, line 62 - column 6, line 11; figures	1
A	FR,A,2 666 502 (ROUX) 13 March 1992	
A	FR,A,2 334 488 (MEADOX MEDICAL) 8 July 1977	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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1

Date of the actual completion of the international search	Date of mailing of the international search report
10 November 1994	21. 11. 94

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Sánchez y Sánchez, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GR94/00019

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 7
because they relate to subject matter not required to be searched by this Authority, namely:
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2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. .onal Application No
PCT/GR 94/00019

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4313231	02-02-82	NONE		
US-A-5123919	23-06-92	NONE		
US-A-5178634	12-01-93	US-A-	5314468	24-05-94
FR-A-2666502	13-03-92	NONE		
FR-A-2334488	08-07-77	DE-A-	2616833	16-06-77
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		NL-A-	7603516	10-06-77